

* NOTICES *

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EXAMPLE

[Example]

(Example 1) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 10. Subsequently, 20.4g of water was put in and closed to the reactor, and it scavenged for 15 minutes the rate for 400 cc/with ultrapure-water helium. Starting heating, the interior of a cavity 20 reached the temperature of 282 degrees C, and pressure 925 psi after 59 minutes. Subsequently, aeration of the reactor 10 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. X-ray diffraction analysis of the processed implant showed that covering contained 94.5% of crystalline **** apatites, 4.7% of amorphism calcium phosphate, and calcium(OH) 2 0.8%. TCP, TTCP, or CaO was not detected at all. The processed implant was put into distilled water, and it agitated at the room temperature for 2 hours, and was immersed twice for 30 seconds into a new acetone. The implant which carried out steam treatment by X-ray diffraction analysis is 0.4% of calcium (OH)2. It turned out that it contains.

[0070] (Example 2) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 10. Subsequently, 10.0g of water was put in and closed to the reactor, and it scavenged for 15 minutes the rate for 400 cc/with ultrapure-water helium. Starting heating, the interior of a cavity 20 reached the temperature of 300 degrees C, and pressure 390 psi after 40 minutes. Subsequently, aeration of the reactor 10 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. X-ray diffraction analysis of the processed implant showed that covering contained 70.6% of crystalline **** apatites, 25.8% of amorphism calcium phosphate, calcium(OH) 2 3.0%, and CaO0.7%. TCP or TTCP was not detected at all. The processed implant was put into distilled water, and it agitated at the room temperature for 2 hours, and was immersed twice for 30 seconds into a new acetone. The implant which carried out steam treatment by X-ray diffraction analysis is 1.2% of calcium (OH)2. And it turned out that 0.5% of CaO is included.

[0071] (Example 3) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 10. Subsequently, 23g of water was put in and closed to the reactor, and it scavenged for 15 minutes the rate for 400 cc/with ultrapure-water helium. Starting heating, the interior of a cavity 20 reached the temperature of 170 degrees C after 59 minutes. temperature -- 170 degrees C -- for 135 minutes -- holding -- a place -- a pressure -- 160 -- psi(s) were reached. Subsequently, aeration of the reactor 10 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. X-ray diffraction analysis of the processed implant showed that covering contained 88.0% of crystalline **** apatites, 10.8% of amorphism calcium phosphate, and calcium(OH) 2 1.1%. TCP, TTCP, or

CaO was not detected at all. The processed implant was put into distilled water, and it agitated at the room temperature for 2 hours, and was immersed twice for 30 seconds into a new acetone. The implant which carried out steam treatment by X-ray diffraction analysis is 0.3% of calcium (OH)₂. It turned out that it contains.

[0072] (Example 4) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 10. Subsequently, 12.3g of water was put in and closed to the reactor, and it scavenged for 15 minutes the rate for 400 cc/with ultrapure-water helium. Starting heating, the interior of a cavity 20 reached the temperature of 206 degrees C after 44 minutes. temperature -- 206 degrees C -- for 45 minutes -- holding -- a place -- a pressure -- 250 psi -- having reached . Subsequently, aeration of the reactor 10 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. X-ray diffraction analysis of the processed implant showed that covering contained 90.2% of crystalline **** apatites, 8.8% of amorphism calcium phosphate, and calcium(OH)₂ 0.9%. TCP, TTCP, or CaO was not detected at all. The processed implant was put into distilled water, and it agitated at the room temperature for 2 hours, and was immersed twice for 30 seconds into a new acetone. The implant which carried out steam treatment by X-ray diffraction analysis is 0.6% of calcium (OH)₂. It turned out that it contains.

[0073] (Example 5) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 10. Subsequently, 20g of water was put in and closed to the reactor, and it scavenged for 15 minutes the rate for 400 cc/with ultrapure-water helium. Starting heating, the interior of a cavity 20 reached the temperature of 300 degrees C after 60 minutes. temperature -- 300 degrees C -- for 15 minutes -- holding -- a place -- a pressure -- 1100 -- psi(s) were reached. Subsequently, aeration of the reactor 10 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. X-ray diffraction analysis of the processed implant showed that covering contained 97.0% of crystalline **** apatites, 3.0% of amorphism calcium phosphate, and calcium(OH)₂ 0.0%. TCP, TTCP, or CaO was not detected at all. The processed implant was put into distilled water, and it agitated at the room temperature for 2 hours, and was immersed twice for 30 seconds into a new acetone. The implant which carried out steam treatment by X-ray diffraction analysis is 0.0% of calcium (OH)₂. It turned out that it contains.

[0074] The process parameter of the above-mentioned example is shown in the following table. These examples show that the specific combination of a process parameter is required, in order to manufacture HA covering which has desired chemical composition and a desired crystalline content.

[0075]

[Table 1]

パラメータ	実施例				
	1	2	3	4	5
ヘリウム	400cc/分	400cc/分	400cc/分	400cc/分	400cc/分
掃気速度					好ましい
ヘリウム	15分	15分	15分	15分	15分
掃気時間					
水の量	20.4g	10.0g	23.0g	12.3g	20g
加熱時間	59分	40分	30分	44分	60分
最終温度	282℃	300℃	170℃	206℃	300℃
最終圧力	925 psi	390 psi	160 psi	250 psi	1100 psi
保持時間	0分	0分	135分	45分	15分
H ₂ O	2時間	2時間	2時間	2時間	2時間
浸出時間					
被覆成分	被覆組成物				
	プラズマスプレー後 → 熱/蒸気処理後				
結晶性HA	45.3→94.5	28.8→70.6	44.0→88.0	46.2→90.2	X→97.0
ACP	22.0→4.7	52.3→25.8	42.1→10.8	40.0→8.8	X→3.0
TCP	7.6→0.0	9.0→0.0	7.9→0.0	7.6→0.0	X→0.0
TTCP	4.7→0.0	8.0→0.0	5.3→0.0	5.7→0.0	X→0.0
被覆成分	被覆組成物				
	プラズマスプレー後 → 熱/蒸気/浸出処理後				
CaO	0.4→0.0	2.0→0.5	0.8→0.0	0.6→0.0	X→0.0
Ca(OH) ₂	0.0→0.0	0.0→1.2	0.0→0.3	0.0→0.6	X→0.0

[0076] The following example explains combination with the desirable process parameter of the reactor shown in drawing 2. The implant used in the following example has a property similar to the implant explained about drawing 1.

[0077] (Example 6) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 100. Subsequently, 200 cc of water was put in and closed to the reactor, and it scavenged for 20 minutes at the rate of 17.7lpm with the ultrapure-water argon. In 15 minutes, the ebullition time amount of water started heating. The interior of a cavity reached the temperature of about 300 degrees C, and the residence time was for 10 minutes. Subsequently, aeration of the reactor 100 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. The processed implant was put into distilled water, and by agitating-speed 50 rpm, it agitated at the room temperature for 2 hours, and into an acetone new subsequently, it reached for 1 minute, respectively and was immersed twice for 5 minutes.

[0078] It examined 3 times by the process parameter of this example. The result of each time is shown in the following table.

[0079]

[Table 2]

被覆成分	初期から最終の組成 (%)		
	第1回	第2回	第3回
結晶性 H A	76.8→95.3	79.7→96.1	74.4→97.6
A C P	13.7→4.7	12.0→3.9	17.8→2.0
β -T C P	2.1→0.0	1.9→0.0	2.1→0.0
α -T C P	0.7→0.0	0.3→0.0	0.5→0.0
T T C P	5.9→0.0	5.1→0.0	4.5→0.0
C a O	1.0→0.0	0.9→0.0	0.7→0.0
C a (O H) ₂	0.0→0.0	0.0→0.0	0.0→0.3
C a C O ₃	0.0→0.0	0.0→0.0	0.0→0.0
平均	結晶性 H A : 77.0→96.3		
	A C P : 14.5→3.5		
	可溶性層 : 8.6→0.1		

[0080] Covering on the implant which has obtained the desirable result the 3rd time and was processed is 97.6% of crystalline **** apatite, 2.0% of amorphism calcium phosphate, and 0.3% of calcium (OH)₂. It turned out that it contains. TCP, TTCP, and CaO or CaCO₃ It was not detected at all.

[0081] The above-mentioned example shows that temperature is about 170 degrees C - 300 degrees C. Probably, it will be clear to make temperature increase to obtaining a high crystallinity covering component.

[0082] Drawing 4 shows the typical prosthetic implant 300 processed by the approach of this invention. Prosthetic implant 300 contains the long and slender base material 302 of a cylindrical shape in the real target which consists of a titanium alloy of biota compatibility. The outside front face 304 of a base material 302 is covered with the glue line 306 which comes to contain a crystalline **** apatite substantially. a layer 306 -- desirable -- at least -- about 90% of the weight of a crystalline **** apatite -- more -- desirable -- at least -- about 95% of the weight of a crystalline **** apatite -- about 97% of the weight of a crystalline **** apatite is included at least most preferably. As for a layer 306, it is desirable that a calcium oxide, a calcium hydroxide, and a calcium carbonate are not included substantially. The vocabulary "it does not contain substantially" used here means not exceeding about 1% of the weight of a crystalline fusibility layer.

[0083] The implant 300 should be noticed about it being an example of prosthetic implant. This contractor can also process the implant of other well-known classes, prosthetic implant, and the supplement organ in which other embedding is possible by the approach of this invention. The implant of drawing 4 includes the hole 308 with the coaxial screw thread of the center opened by the end 310 about this. Two or more splines 312 used for touching the auxiliary parts (not shown in drawing) and the interface like abutments from this end are extended upwards. This spline interface is indicated by U.S. Pat. No. 5,449,291 entitled "the prosthetic implant device in which it has feedback with a feel" at the detail.

[0084] Since deformation of a certain kind can be carried out to above-mentioned equipment and an above-mentioned approach, without separating from the range of this invention, it is contained in explanation, or the matters shown in the attached drawing are [no] for explanation, and restrict this invention.

[Translation done.]

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Field of the Invention] Since in more detail promotes the unification with a bone about the supplement implant in which the embedding for bone anabolism is possible, and its art, this invention relates [generally] to the art of the implant which has **** apatite covering, and these implant that carried out plasma spraying of the **** apatite.

[0002]

[Description of the Prior Art] The wave of ED is turned to manufacture of prosthetic implant with very high human being's organization and biota compatibility with a bone from the 1980s. One of the targets of this technique is manufacturing the implant possible nearest to a natural osseous tissue. Such implant will more fully unite with the existing osseous tissue, and will promote growth of the new bone in the perimeter of the implant.

[0003] A biological apatite is one sort of the main compounds produced for human being's bone and gear tooth. The synthetic gestalt of this mineral **** apatite (HA) is very well alike in the apatite produced automatically. Since there is this similarity of Composition HA and a natural apatite, the scientist is investigating the object for the dentistry of HA, and the application to the implant for orthopedics. After one of the targets of this research embeds, it is manufacturing the implant easily united with a surrounding bone and an organization.

[0004] The thing with the first prosthetic implant which has tried use of a synthetic apatite is altogether formed from sintered HA. These implant had the outstanding bioactive, after embedding. However, the scientist got to know that it was common for the mechanical property of these implant to be inadequate. For example, after the prosthetic implant formed only from HA being unable to bear a normal physiological load but embedding it to a patient, produces a crack or it tends to be damaged.

[0005] Then, research was turned to metal implant like the implant formed from the titanium base material. The metal implant is strong and can bear the physiological load which acts on the bone of a jaw. However, the implant formed only from HA does not unite these implant with a bone more quickly. Subsequently, cautions were turned to covering of the metal implant by HA.

[0006] Plasma spraying is one of the well-known approaches for covering the metal implant with HA. By this approach, the flow of mixed gas passes an elevated-temperature electric arc, and gas is ionized by the plasma flame with an arc. Then, if crystalline HA raw material powder is supplied into this flow, HA will collide on the outside front face of the implant in the state of melting. A spray adheres to a front face and forms comparatively thin covering of HA.

[0007] The metal implant which carried out HA covering shows the advantage of both the pure metal implant and pure HA implant. These implant itself is strong, an osseous tissue forms the front face of covering, and powerful association, and it promotes the unification with biota compatibility and a bone. However, though regrettable, plasma spraying has some important faults.

[0008] Plasma spraying exposes HA to very high temperature, therefore change which is not desirable is induced by a gestalt and chemical presentation. A special problem arises by these change. Especially crystalline high HA has the stability in a glass instrument far higher than amorphism HA. Before the spray of the good HA raw material is carried out, it has a perfect crystalline form. With the temperature accompanying plasma spraying, as for HA, the crystal structure is partially changed into few [far] gestalten from the pure crystalline gestalt. Generally the amorphous gestalt of this HA is called amorphism calcium phosphate (ACP). Crystalline HA raw material is also partially changed into other crystalline components (alpha-TCP and beta-TCP are included), for example, tricalcium phosphate, phosphoric-acid 4 calcium (TTCP), and a calcium oxide (CaO) in the case of plasma spraying. Since the solubility to those water solutions is quite higher than Crystallinity HA, these impurities can be collectively called a crystalline meltable phase.

[0009] The impurity produced from plasma spraying of HA raises some problems. In the first place, an impurity tends to dissolve during a surrounding organization. Therefore, since a part of covering is lost, covering to which plasma spraying of [on the implant] was carried out collapses with time amount. The dissolution of HA covering suggests that the bioactive interface between a bone and the implant becomes not much effective less. The dissolution has actually weakened [the interface between the implant and a surrounding bone, and] the interface between covering and the implant in more detail. Furthermore, the thing with these impurities has hemolysis within a glass instrument. It is shown that especially CaO causes hemolysis. Therefore, many cautions are turned to converting into Crystallinity HA the impurity which exists on covering, and returning it.

[0010] Law is heat treatment, while being used in order to recover the high crystallinity HA content of covering which carried out plasma spraying. The covered implant is heated at least on comparatively high temperature and a general target in air at about 500-600 degrees C in the case of this approach. An elevated temperature recrystallizes a part of amorphism HA, and a part of meltable phase is converted into coincidence by Crystallinity HA according to it. However, the fatigue strength of a titanium-alloy base material falls to coincidence according to an elevated temperature. Since the implant needs to maintain those reinforcement and structural integrity, heat treatment is not an appropriate approach.

[0011] Another approach used for manufacture of the high crystallinity HA is hot water processing. One of the advantages of this approach is that the temperature under processing is generally lower than temperature required for the heat treatment approach. Consequently, degradation of a metal base does not take place.

[0012] Hot water processing of a certain kind is performed in an autoclave. For example, the implant which carried out HA covering is put in into an autoclave with water or a water solution. Subsequently, the temperature and the pressure of an autoclave are made to increase. With a temperature rise, a pressure increases [water] instead of a steam. The implant is placed into the environment of elevated-temperature high pressure, and a crystalline phase formless in the meantime and meltable is converted into Crystallinity HA.

[0013] One of the faults relevant to current hot water processing is that the percentage of the

impurity containing a crystalline phase with the processed formless and meltable implant is comparatively high. For example, a certain kind of ACP does not recrystallize. Therefore, the implant with the very high percentage of Crystallinity HA is not obtained. To embedding, the prosthetic implant of high crystallinity is desirable.

[0014] The total processing time of a hot water process of another fault is quite a *****. For example, hot water processing of a certain kind needs to expose the implant to an elevated temperature and high pressure when for between or many days. It is impossible to process many implant by these approaches for a short time.

[0015] As another fault, the current hot water approach does not affect all the impurities that exist after plasma spraying. Consequently, the processed implant has many crystalline layer contents formless and more nearly meltable than what was processed by other approaches. Therefore, also after processing is completed, the impurity of a comparatively high percentage remains.

[0016] As another fault, hot water processing of a certain kind needs comparatively high temperature. This high temperature reduces the reinforcement of a metal base to the appearance indicated by the heat-treating method.

[0017] As another fault, hot water processing of a certain kind needs too much operating condition like high pressure. or [that the equipment which can give the hyperbaric atmosphere of the degree of pole requires cost for processing many implant too much] -- or it is not practical.

[0018] As another fault, the long thing exceeding several hours or several days to do for time amount immersion is needed in a water solution in the implant by hot water processing of a certain kind. These processings dissolve non-HA component alternatively, and they are designed so that it may be unhurt and may leave the desired matter. By immersing the implant in this appearance, it may have a bad influence on the reinforcement of adhesives covering, and the tensile strength of the implant may be weakened, or the side effect which is not desirable as for others may be produced.

[0019] As still more nearly another fault, water uses the steam environment containing a carbon dioxide (CO₂) by hot water processing of a certain kind. A carbon dioxide reacts with HA covering on the implant, and forms a calcium carbonate (CaCO₃).

[0020]

[Elements of the Invention] This invention relates to prosthetic implant, a supplement organ for orthopedics, etc. which have crystalline high **** apatite (HA) covering. The implant is first covered with HA using a well-known plasma-spraying technique. After carrying out plasma spraying of HA, the implant is applied to 2 process process including hot water down stream processing and an extraction process. According to these two processes, the implant which has high crystallinity HA covering with very few contents of amorphism calcium phosphate (ACP) is manufactured. This covering does not contain substantially a calcium hydroxide, a calcium oxide, and a calcium carbonate, either.

[0021] The implant is put in into the container which can acquire an elevated-temperature hyperbaric atmosphere, or equipment in the case of hot water down stream processing. Subsequently, the implant is heated under existence of a steam ambient atmosphere and pressurization conditions. If desired temperature is reached, the temperature was able to be decided beforehand and time amount maintenance will be carried out. Aeration of a container or the equipment is carried out, and the implant is cooled. Then, the implant is processed at an extraction process. At this process, the water of a liquid was decided on beforehand and

time amount exposure of the implant is carried out. Subsequently, it exposes to an organic solvent like an acetone immediately, and, subsequently the air-drying of the implant is carried out.

[0022] As one of the advantages, the processed implant has covering with the high percentage of Crystallinity HA. In this condition, ACP and a meltable crystalline phase impurity are converted into Crystallinity HA almost completely completely, or are dissolving from covering. For example, about 97 % of the weight of surface coating is Crystallinity HA.

[0023] As another advantage, the total processing time required for processing of the implant after plasma spraying is comparatively short. The processing time including both hot water down stream processing and an extraction process can be shortened in about several hours. Therefore, many implant can be applied to this processing cycle by between specific time amount.

[0024] As another advantage, this approach processes many crystalline impurities. Covering contains a calcium oxide after plasma spraying in many cases. In the case of hot water down stream processing, a calcium oxide is not fully converted into Crystallinity HA, but some calcium oxides are converted into a calcium hydroxide. A calcium hydroxide dissolves into an extraction process. In this way, the processed implant contains neither a calcium oxide nor a calcium hydroxide.

[0025] As another advantage, hot water processing of this invention does not need comparatively high temperature. Therefore, the reinforcement of a metal base does not fall.

[0026] As another advantage, hot water down stream processing does not need a superfluous pressure, in order to obtain crystalline high HA covering. For example, under a specific actuation situation, a pressure can be changed to about 1100 psi from about 250 psi, and the surface coating of at least 90% of the weight of the crystallinity HA can be attained.

Therefore, the equipment which can bear an impractical pressure is not needed. An extraction process can be performed as still more nearly another advantage in about 2 hours. therefore, the tensile strength of the implant which does a bad influence for the implant into water or a water solution at the adhesion reinforcement of covering is reduced, or like [which produces the side effect which is not desirable as for others] is comparatively long -- time amount immersion is not carried out.

[0027] As still more nearly another advantage, before processing the implant in a steam environment in the case of hot water down stream processing, the dissolved carbon dioxide is removed from water. Therefore, a carbon dioxide reacts with HA covering and does not form a calcium carbonate.

[0028] This invention includes the equipment and the approach of having the combination of the structure and the component which are explained to a detail, and arrangement of components in below. The essence and the purpose of this invention are explained to a detail, referring to the drawing of attachment in the following.

[0029] Drawing 1 shows the reactor 10 for performing the approach of this invention. Any of various equipments well-known to this contractor like the autoclave which can build an elevated-temperature hyperbaric atmosphere, the container which can be pressurized, or ** are sufficient as a reactor 10. A reactor 10 has a thick wall, is the container 12 which can pressurize a cylindrical shape on the whole, and includes a fundus 14 and covering 16. A fundus 14 includes the side attachment wall 18 of the cylindrical shape which limits the cavity 20 of a cylindrical shape to the interior. The cavity 20 is opened in the upper limit section of a fundus 14, and is closed in the lower limit section. It really connects with a side attachment

wall 18, and the even bottom wall 22 forms the pars-basilaris-ossis-occipitalis case. It really connects with a side attachment wall 18, and the cyclic flange 24 forms the upper part of elongation and a fundus 14 in a radial toward outside from a side attachment wall. The wall of a container 12 is built with the ingredient which has sufficient reinforcement to give the cavity which maintains an elevated-temperature hyperbaric atmosphere, and biota compatibility. These walls can be built for example, with 316 stainless steel, and can give the cavity 20 of volume about 276 legislation cm.

[0030] Covering 16 is the disk even on the whole built so that it might seal to the cyclic flange 24. Between covering 16 and a flange 24, a heat-resistant gasket (not shown in drawing), for example, graphite gasket **, is arranged, and a proof-pressure seal is formed. Two or more holes (not shown in drawing) which set spacing and have been arranged in the direction of a perimeter passed along covering 16, and are extended in the flange 24. It can let the hole which set these spacing and has been arranged pass, and the bolt 26 with the screw thread with which plurality corresponds can be arranged. If a bolt 26 is bound tight, it will engage with covering 16, a gasket will be pressed between covering and a flange 24, and proof-pressure seal of the cavity 20 will be carried out.

[0031] Two or more conduits 30, 32, and 34 are extended through covering 16. These conduits are sealed to covering, and are connected with a cavity 20, and the path used as the inlet port of gas or other fluids and an outlet is given. each -- conduits 30, 32, and 34 are equipped with the bulbs 36, 38, and 40 by which it corresponds for stopping or controlling the flow of gas or a fluid, respectively. The outside end 42 of a conduit 30 includes the inlet port 47 which connected the outside end 46 of a conduit 32 to the source of supply (not shown in drawing) of super-high grade inert gas, for example, helium, or argon ** including an air hole 44. After this gas flows in into a cavity 20 through a conduit 32, it can be exhausted from a cavity through a conduit 30. The outside end 48 of a conduit 34 contains the gage 50 which measures the gas pressure in a cavity 20.

[0032] The path 52 for thermometries (thermal well) is sealed to elongation and covering 16 through covering 16. This path contains the conduit with which an end 54 is extended in a cavity 20 and elongation and the second end 56 are extended besides the pressurized container 12. It has prevented that close a path 52 at the end 54 and gas or a fluid connects it with the exterior of a container 12 through a conduit. As shown in drawing, the end 54 is thermally connected with the building envelope of elongation and a cavity into a cavity 20. A sufficient room is between an end 54 and the internal side attachment wall of a cavity 20, and the suitable insulation for thermal measurement documentation is maintained.

[0033] A thermocouple 55 is arranged in an end 54 and it is exposed to the ambient temperature of the cavernous 20 interior. A thermocouple generates the electrical potential difference in direct proportion to the temperature inside a cavity. Including two wires, these wires formed the joint and have connected the thermocouple to elongation and a proportional integral differential (PID) control unit (not shown in drawing) along with the die length of a path 52. A control unit changes the generated electrical potential difference into the temperature scale suitable for a display, and controls operation of the heat source of a reaction 10. The suitable PID-control equipment for such an application is Minnesota and the model 942 currently manufactured by Watlow of Winona.

[0034] The dismountable stores dept. 60 is also arranged in the cavity 20. This stores dept. contains the container of the cylindrical shape which has the open upper part 62. The water of the liquid of a high grade is put in into a stores dept. 60, and it exposes to the building

envelope of a cavity 20.

[0035] The electric heating jacket 64 encloses the exterior of a container, and is used for heating the interior of a cavity 20. In the case of heating, a thermocouple 55 senses the temperature inside a cavity and this information is sent to PID-control equipment. If the temperature of a cavity approaches a desired value, a control device will reduce heat dissipation of a heating jacket 64, or will stop, and will prevent an excess of desired temperature.

[0036] The ceramic heat insulator 66 encloses the container 12 and the heating jacket 64. preferably, a heat insulator is enough to insulate a container -- it has the thickness of about 1 inch, and the consistency of about 8 pound per cubic foot at least.

[0037] Drawing 2 illustrates another reactor 100 for performing the approach of this invention, and shows a device required to control operation of a reactor more to a detail.

[0038] Generally a reactor 100 contains the container 102 including a fundus 104 and covering 106 in which the thick pressurization of a wall is possible. A fundus 104 and covering 106 limit a cavity 108. If covering 106 is removed from a fundus 104, it can arrive at a cavity. A heater 110 heats a cavity 108 to desired temperature in the case of operation.

[0039] Covering 106 is built so that it may suit densely to a fundus 104. A heat-resistant gasket (not shown in drawing) is arranged between covering 106 and a fundus 104, and forms a proof-pressure seal. Two or more bolts (not shown in drawing) pass along covering and a fundus, and this proof-pressure seal to a cavity 108 is performed.

[0040] Two or more conduits and Rhine form some reactors 100. These conduits and Rhine are controlling and maintaining the reactor so that it may explain to a detail by the following.

[0041] Water Rhine 120 passed along covering 106, and is extended to two or more cooling coils 122. These coils have connected the inside of a cavity 108 to wastewater Rhine 123 of the exterior which gives the outlet of elongation and a cooling coil. Rhine 120 contains a flow meter 124 and a bulb 126. A flowmeter 124 measures the stream passing through Rhine 120. A stream can be adjusted by the bulb 126.

[0042] Next, compressed-air Rhine 130 connects with water Rhine 120, and is also connecting with the cooling coil 122. Rhine 130 contains a compressor 132, an air resister 134, and a bulb 136. A compressor 132 compresses the flowing air which was filtered. Subsequently, this air compressed and filtered passes along the regulator 134 which adjusts and controls airstream. This airstream can be adjusted by the bulb 136.

[0043] The argon gas line 140 passes along covering 106, and is connecting with the cavity 108. A gas governor 142 adjusts the gas stream of Rhine 140. After a regulator, gas passes along the flow meter 144 which measures and controls a flow rate, and, subsequently passes along two bulbs 146 and 148. These two bulbs adjust the gas stream passing through Rhine 140. Furthermore, the conduit 150 has connected with elongation and a gas line 140 from air Rhine 130. This conduit contains a bulb 152.

[0044] The system of the bulb connecting with air and a gas line controls the flow of the gas to the inside of a cavity 108. If bulbs 152 and 148 open and a bulb 146 closes, the compressed air cannot flow in into a cavity 108, and gas cannot flow in into it. If bulbs 146 and 148 open and a bulb 152 closes, gas cannot flow in into a cavity 108 and air cannot flow in into it.

[0045] Supervising carefully a pressure, temperature, and the steamy content of the cavernous 108 interior during operation of a reactor 100, aeration Rhine 160 which should be adjusted contains elongation and a bulb 162 through covering 106. When the bulb 162 is

open, using Rhine 160, a steam is missed from a cavity 108 or gas can be eliminated.

[0046] The safety line 164 is also connected with elongation and a cavity 108 through covering 106. Rhine 164 contains the rupture disk 166 which prevents superfluous are recording of the pressure in a cavity 108. If the pressure in a cavity reaches a dangerous level, a plate 166 will explode and this pressure will be emitted through Rhine 164.

[0047] As shown in drawing, the pressure line 170 is extended in the cavity 108 through covering 106, and contains two pressure transducers 172 and 174. A transducer 172 measures the pressure in a cavity 108, for example, is good with the gage of an analog mold. A converter 174 also measures the pressure in a cavity 108, and is good at an electric inverter. Furthermore, process ***** 176 is connecting with the transducer 174, and gives digital pressure read-out.

[0048] The path 180 for thermometries is extended in the cavity 108. This path is connected to the process temperature controller 184 including the thermocouple 182. This control device can display the digital readout of the temperature of the cavernous 108 interior, and can program it to control a heating parameter still like heating time, the holding time, and temperature. As shown in drawing, the indicator 176 and the control device 184 are connected to the chart recorder 186. This recorder records the information on both a pressure and temperature, and gives data with time.

[0049] Another thermocouple 190 is also connected with the cavity 108. This thermocouple is connected to the epidermis temperature controller 192 which prevents that superfluous temperature arises in a cavity 108. Control units 184 and 192 are connected to a power source 194. This power source is supplying electric power also to the heater.

[0050] Drawing 3 shows the whole approach of this invention. This approach includes the extraction process which generally follows hot water down stream processing and it.

[0051] The implant is prepared with block 200. Next, block 202 covers the implant by HA. Although the implant is covered using plasma spraying, such a covering technique is widely known for this field. Although HA powder is used in the case of a spray process, the content of Crystallinity HA is desirable and most of this powder is 100%. the implant after carrying out the spray of the implant -- crystallinity -- both various impurities including HA, ACP, and a fusibility crystallinity phase are included. The percentage of an impurity changes with factors of many like the degree of crystallinity of HA to be used, and the parameter in the case of plasma spraying.

[0052] After carrying out the spray of the implant, as shown in block 204, it can apply to hot water down stream processing of this approach. Blocks 206-212 show this process to a detail.

[0053] A reactor is prepared with block 206. At this time, the implant is sealed in a container, and establishes and sets up a desired process parameter. In a process parameter, determining-the holding time over amount [of the water in replacing the air for example, in a container with inert gas like helium or an argon and a container], rate [which heats and cools the implant], maximum-pressure, temperature, specific pressure, and temperature ** is contained.

[0054] Furthermore, before starting heating, the dissolved carbon dioxide (CO₂) should be removed from the water in a container. A carbon dioxide is HA covering on the implant, especially CaO or calcium (OH)₂. It may react and a calcium carbonate (CaCO₃) may be formed. There are some approaches for removing a carbon dioxide from water, and these approaches are well-known to this contractor. For example, there is ebullition of water, an approach (approach called spur JINGU) of making it foam by gas (for it to be (like helium))

through water, or a method of processing water with deionization equipment.

[0055] Subsequently, as shown in block 208, the implant is heated to desired temperature. At this time, the pressure in a container increases and water carries out a phase change from a liquid to saturated steam.

[0056] next, it is shown in block 210 -- as -- the implant -- time amount maintenance of specification [the highest temperature and the highest pressure] -- it carries out. For example, it is good to hold the implant for 15 minutes at pressure 1100 psi and the temperature of 300 degrees C. Then, as shown in block 212, a steam is discharged and a container and the implant are cooled.

[0057] After hot water down stream processing is completed, the implant should become about 90% of the weight, even if there is little crystallinity HA. The calcium oxide which exists after plasma spraying is converted into a calcium hydroxide.

[0058] As shown in block 214, the following process is initiation of extraction processing. By extraction processing, the calcium hydroxide which is not desirable is removed from covering, and it leaves covering which comes to contain Crystallinity HA and little ACP substantially.

[0059] In the case of extraction processing, as shown in block 216, the implant is exposed to water. Water dissolves a calcium hydroxide from covering. On the other hand, law is a thing which expose the implant to water and which is immersed in the water of a liquid condition in the implant. Preferably, water is agitated and the implant is contacted in water for a long time for about 2 hours. This time amount should be sufficient time amount to dissolve as many calcium hydroxides as possible [substantial] in the implant or covering, without doing the side effect which is not desirable.

[0060] Immediately after exposing the implant to water, the implant is exposed to an anhydrous acetone as shown in block 218. An acetone acts so that all the residual water left behind on the implant may be removed. The implant is good to be immersed for about 60 seconds for example, during an acetone bath. Probably, under an acetone bath needs to be immersed to remove superfluous water from the implant.

[0061] The air-drying of the implant is carried out to the last with block 220. An acetone evaporates from covering in the case of an air-drying.

[0062] After hot water processing and extraction down stream processing are completed, the implant should contain the base material which has HA covering of high crystallinity. About 90 - 100 % of the weight is Crystallinity HA, and covering does not contain substantially a calcium oxide, a calcium hydroxide, a calcium carbonate, and the crystalline phase of fusibility.

[0063] It returns to drawing 1 and the desirable embodiment of this invention is explained more to a detail. Plasma spraying of the **** apatite is carried out to the outside of supplement organic ** in which the implant, for example, prosthetic implant, or embedding is possible. The plasma-spraying technique is well known by this contractor. After carrying out HA covering at the implant, covering 16 is removed from a flange 24 and the implant is put in into the cavity 20 of a container 12. Two or more implant is arranged on the rack in a cavity (not shown in drawing), and it can avoid contacting the wall of a container 12 or an inside front face, and directly. Subsequently, the liquefied water of the high grade of the amount of specification is put in into a stores dept. 60. As for this water, it is desirable to process by the well-known approach to this contractor like ebullition, helium spur JINGU, or deionization, and to remove a carbon dioxide. It prevents that water with a liquefied stores dept. contacts the inside directly. Covering 16 is carried on a flange 24, a bolt 26 is bound tight, covering 16 is strongly drawn to a flange 24, and the proof-pressure seal of high quality is formed. After

closing a container 12, the bulbs 36 and 38 called an aeration bulb and a gas supply bulb, respectively are opened. ultrapure-water inert gas -- desirable -- helium or argon ** -- a bulb 38 -- a passage -- a cavity 20 -- it flows into inside. The original air ambient atmosphere in a cavity 20 is discharged through the aeration bulb 36 as a result of this gas stream. a gas stream is enough to drive out air of a cavity 20 and leave a completely inactive ambient atmosphere -- time amount maintenance is carried out. The oxidation which may cause discoloration of the surface of metal which the titanium base material exposed by removal of air can be suppressed to the minimum. To the manufacture reactor, it came out enough by the scavenging time for about 15 minutes, and about 1770 cc quantity of gas flow for /, and a certain thing was understood.

[0064] An aeration bulb and a gas supply bulb are closed after scavenging air, and the inert gas ambient atmosphere in a cavity 20 is sealed to a pressure almost equal to atmospheric pressure. A heating jacket is operated and heating of a cavity 20 is started. While [60 minutes] continuing, the internal temperature of a cavity 20 rises in terminal temperature of about 300 degrees C from a room temperature. The phase change of the liquefied water in a stores dept. 60 is carried out to a gas from a liquid, and it produces the ultimate-pressure force of an about 1100pound [/square] inch in a cavity.

[0065] Temperature is held for about 15 minutes at about 300 degrees C. A pressure and temperature fall immediately by opening a bulb 36 after this time amount, and emitting a steam into atmospheric air. Subsequently, a bulb 36 is closed and invasion of air in case a container 12 cools is prevented. It cools until it removes a container 12 from a heating jacket 64 and can remove covering 16 without the danger of doing distortion or damage to a container, safely. When applying for about 45 minutes and cooling in temperature of about 100 degrees C, it came out enough and a certain thing was understood.

[0066] A container 12 is opened after cooling and the rack of the implant or the implant is taken out from a cavity 20. Then, the inside and a rack are immersed in distilled water at a room temperature for about 2 hours. Preferably, water is agitated, or a rack is vibrated and the implant and water are made to exercise relatively. Subsequently, the implant is taken out from distilled water and it is immediately immersed in the first bath of an acetone for about 30 seconds. A rack and the implant are pulled out from the first bath of an acetone, and it is immediately immersed for about 30 seconds during the second bath of a new acetone. An acetone bath can remove all liquefied water from the implant substantially, and can carry out the air-drying of the implant quickly.

[0067] According to the above-mentioned process, about 97% of crystalline **** apatites is included, and it is the crystalline phase and CaCO_3 of a calcium oxide, a calcium hydroxide, and fusibility. **** apatite covering which is not included substantially is obtained. The presentation of covering obtained was measured by X-ray diffraction analysis covering the range of 20 from about 16 degrees to about 40 degrees. The metal base material does not show the remarkable discoloration by oxidation. Furthermore, the adhesion reinforcement between covering and a base material is seldom falling. Although the desirable embodiment of this invention was explained, of course, other process parameters and combination can be used within the limits of this invention. The die length of the holding time of the primary quantity of the water for example, in a stores dept., the temperature in a cavity, the pressure in a cavity, a pressure, and temperature and the time amount which applies the implant to extraction is contained in such a process parameter. One of the important advantages of this invention is that **** apatite covering of purity is obtained about 90 to 97% of the weight by

this approach. Furthermore, covering is the crystalline phase and CaCO_3 of a calcium oxide, a calcium hydroxide, and fusibility. It does not contain substantially. Therefore, although a process parameter is changeable in the case of both the processes of hot water processing and extraction, the implant obtained has at least 90% of crystalline HA covering.

[0068] The following example indicates a part of various combination in which a process parameter is possible. The reactor shown in drawing 1 was used by each of the following example. The implant processed in the following example contains the titanium-alloy split (Ti6aluminum4V) covered with the **** apatite powder applied by the plasma-spraying method. although the raw material of plasma-spraying actuation is 100% crystallinity **** apatite substantially -- covering just behind a spray -- a crystalline **** apatite, an amorphism phase (ACP) and the crystalline phase of fusibility, for example, tricalcium phosphate, (alpha-TCP and beta-TCP are included), phosphoric-acid 4 calcium (TTCP), and a calcium oxide (CaO) -- since -- the becoming impurity is included. The presentation of plasma-spraying covering before subsequent down stream processing contains the crystalline fusibility component which contains the crystalline **** apatite of rough within the limits of the following, i.e., 28% - 46%, 40% - 52% of amorphous **** apatite (ACP), and 12% - 19% of alpha-TCP, beta-TCP, TTCP, and CaO for the following component. About 0.4 - 2.0% of CaO(s) exists. HA degree of crystallinity of these covering of all shows the last degree of crystallinity lower than the degree of crystallinity generally seen to almost all the commercial implant. The covering thickness of these samples is 0.004-0.005", and is twice [about] as thick as the commercial implant. The X-ray diffraction method which analyzes the presentation of covering is indicated by LeGeros, John P., et al., and "ASTM STP 1196."

[0069]

[Example]

(Example 1) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 10. Subsequently, 20.4g of water was put in and closed to the reactor, and it scavenged for 15 minutes the rate for 400 cc/with ultrapure-water helium. Starting heating, the interior of a cavity 20 reached the temperature of 282 degrees C, and pressure 925 psi after 59 minutes. Subsequently, aeration of the reactor 10 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. X-ray diffraction analysis of the processed implant showed that covering contained 94.5% of crystalline **** apatites, 4.7% of amorphism calcium phosphate, and calcium(OH) 2 0.8%. TCP, TTCP, or CaO was not detected at all. The processed implant was put into distilled water, and it agitated at the room temperature for 2 hours, and was immersed twice for 30 seconds into a new acetone. The implant which carried out steam treatment by X-ray diffraction analysis is 0.4% of calcium (OH)2. It turned out that it contains.

[0070] (Example 2) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 10. Subsequently, 10.0g of water was put in and closed to the reactor, and it scavenged for 15 minutes the rate for 400 cc/with ultrapure-water helium. Starting heating, the interior of a cavity 20 reached the temperature of 300 degrees C, and pressure 390 psi after 40 minutes. Subsequently, aeration of the reactor 10 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. X-ray diffraction analysis of the processed implant showed that covering contained 70.6% of crystalline **** apatites, 25.8% of amorphism calcium phosphate, calcium(OH) 2 3.0%, and CaO0.7%. TCP or TTCP was not detected at all. The processed implant was put into distilled water, and it agitated at the room temperature for 2 hours, and was immersed twice for 30 seconds into a

new acetone. The implant which carried out steam treatment by X-ray diffraction analysis is 1.2% of calcium (OH)₂. And it turned out that 0.5% of CaO is included.

[0071] (Example 3) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 10. Subsequently, 23g of water was put in and closed to the reactor, and it scavenged for 15 minutes the rate for 400 cc/with ultrapure-water helium. Starting heating, the interior of a cavity 20 reached the temperature of 170 degrees C after 59 minutes. temperature -- 170 degrees C -- for 135 minutes -- holding -- a place -- a pressure -- 160 -- psi(s) were reached. Subsequently, aeration of the reactor 10 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. X-ray diffraction analysis of the processed implant showed that covering contained 88.0% of crystalline **** apatites, 10.8% of amorphism calcium phosphate, and calcium(OH)₂ 1.1%. TCP, TTCP, or CaO was not detected at all. The processed implant was put into distilled water, and it agitated at the room temperature for 2 hours, and was immersed twice for 30 seconds into a new acetone. The implant which carried out steam treatment by X-ray diffraction analysis is 0.3% of calcium (OH)₂. It turned out that it contains.

[0072] (Example 4) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 10. Subsequently, 12.3g of water was put in and closed to the reactor, and it scavenged for 15 minutes the rate for 400 cc/with ultrapure-water helium. Starting heating, the interior of a cavity 20 reached the temperature of 206 degrees C after 44 minutes. temperature -- 206 degrees C -- for 45 minutes -- holding -- a place -- a pressure -- 250 psi -- having reached . Subsequently, aeration of the reactor 10 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. X-ray diffraction analysis of the processed implant showed that covering contained 90.2% of crystalline **** apatites, 8.8% of amorphism calcium phosphate, and calcium(OH)₂ 0.9%. TCP, TTCP, or CaO was not detected at all. The processed implant was put into distilled water, and it agitated at the room temperature for 2 hours, and was immersed twice for 30 seconds into a new acetone. The implant which carried out steam treatment by X-ray diffraction analysis is 0.6% of calcium (OH)₂. It turned out that it contains.

[0073] (Example 5) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 10. Subsequently, 20g of water was put in and closed to the reactor, and it scavenged for 15 minutes the rate for 400 cc/with ultrapure-water helium. Starting heating, the interior of a cavity 20 reached the temperature of 300 degrees C after 60 minutes. temperature -- 300 degrees C -- for 15 minutes -- holding -- a place -- a pressure -- 1100 -- psi(s) were reached. Subsequently, aeration of the reactor 10 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. X-ray diffraction analysis of the processed implant showed that covering contained 97.0% of crystalline **** apatites, 3.0% of amorphism calcium phosphate, and calcium(OH)₂ 0.0%. TCP, TTCP, or CaO was not detected at all. The processed implant was put into distilled water, and it agitated at the room temperature for 2 hours, and was immersed twice for 30 seconds into a new acetone. The implant which carried out steam treatment by X-ray diffraction analysis is 0.0% of calcium (OH)₂. It turned out that it contains.

[0074] The process parameter of the above-mentioned example is shown in the following table. These examples show that the specific combination of a process parameter is required, in order to manufacture HA covering which has desired chemical composition and a desired crystalline content.

[0075]

[Table 1]

パラメータ	実施例				
	1	2	3	4	5
ヘリウム	400cc/分	400cc/分	400cc/分	400cc/分	400cc/分
掃気速度					好ましい
ヘリウム	15分	15分	15分	15分	15分
掃気時間					
水の量	20.4g	10.0g	23.0g	12.3g	20g
加熱時間	59分	40分	30分	44分	60分
最終温度	282℃	300℃	170℃	206℃	300℃
最終圧力	925 psi	390 psi	160 psi	250 psi	1100 psi
保持時間	0分	0分	135分	45分	15分
H ₂ O	2時間	2時間	2時間	2時間	2時間
浸出時間					
被覆成分					
被覆組成物					
プラズマスプレー後 → 熱/蒸気処理後					
結晶性HA	45.3→94.5	28.8→70.6	44.0→88.0	46.2→90.2	X→97.0
ACP	22.0→4.7	52.3→25.8	42.1→10.8	40.0→8.8	X→3.0
TCP	7.6→0.0	9.0→0.0	7.9→0.0	7.6→0.0	X→0.0
TTCP	4.7→0.0	8.0→0.0	5.3→0.0	5.7→0.0	X→0.0
被覆成分					
被覆組成物					
プラズマスプレー後 → 熱/蒸気/浸出処理後					
CaO	0.4→0.0	2.0→0.5	0.8→0.0	0.6→0.0	X→0.0
Ca(OH) ₂	0.0→0.0	0.0→1.2	0.0→0.3	0.0→0.6	X→0.0

[0076] The following example explains combination with the desirable process parameter of the reactor shown in drawing 2. The implant used in the following example has a property similar to the implant explained about drawing 1.

[0077] (Example 6) Plasma spraying of HA was carried out to the titanium-alloy implant, and it put in into the reactor 100. Subsequently, 200 cc of water was put in and closed to the reactor, and it scavenged for 20 minutes at the rate of 17.7lpm with the ultrapure-water argon. In 15 minutes, the ebullition time amount of water started heating. The interior of a cavity reached the temperature of about 300 degrees C, and the residence time was for 10 minutes. Subsequently, aeration of the reactor 100 was carried out to the atmospheric pressure, and it was picked out from the heating jacket 50. The processed implant was put into distilled water, and by agitating-speed 50 rpm, it agitated at the room temperature for 2 hours, and into an acetone new subsequently, it reached for 1 minute, respectively and was immersed twice for 5 minutes.

[0078] It examined 3 times by the process parameter of this example. The result of each time is shown in the following table.

[0079]

[Table 2]

被覆成分	初期から最終の組成 (%)		
	第1回	第2回	第3回
結晶性HA	76.8→95.3	79.7→96.1	74.4→97.6
ACP	13.7→4.7	12.0→3.9	17.8→2.0
β -TCP	2.1→0.0	1.9→0.0	2.1→0.0
α -TCP	0.7→0.0	0.3→0.0	0.5→0.0
TTCP	5.9→0.0	5.1→0.0	4.5→0.0
CaO	1.0→0.0	0.9→0.0	0.7→0.0
Ca(OH) ₂	0.0→0.0	0.0→0.0	0.0→0.3
CaCO ₃	0.0→0.0	0.0→0.0	0.0→0.0
平均	結晶性HA : 77.0→96.3		
	ACP : 14.5→3.5		
	可溶性層 : 8.6→0.1		

[0080] Covering on the implant which has obtained the desirable result the 3rd time and was processed is 97.6% of crystalline **** apatite, 2.0% of amorphism calcium phosphate, and 0.3% of calcium (OH)₂. It turned out that it contains. TCP, TTCP, and CaO or CaCO₃ It was not detected at all.

[0081] The above-mentioned example shows that temperature is about 170 degrees C - 300 degrees C. Probably, it will be clear to make temperature increase to obtaining a high crystallinity covering component.

[0082] Drawing 4 shows the typical prosthetic implant 300 processed by the approach of this invention. Prosthetic implant 300 contains the long and slender base material 302 of a cylindrical shape in the real target which consists of a titanium alloy of biota compatibility. The outside front face 304 of a base material 302 is covered with the glue line 306 which comes to contain a crystalline **** apatite substantially. a layer 306 -- desirable -- at least -- about 90% of the weight of a crystalline **** apatite -- more -- desirable -- at least -- about 95% of the weight of a crystalline **** apatite -- about 97% of the weight of a crystalline **** apatite is included at least most preferably. As for a layer 306, it is desirable that a calcium oxide, a calcium hydroxide, and a calcium carbonate are not included substantially. The vocabulary "it does not contain substantially" used here means not exceeding about 1% of the weight of a crystalline fusibility layer.

[0083] The implant 300 should be noticed about it being an example of prosthetic implant. This contractor can also process the implant of other well-known classes, prosthetic implant, and the supplement organ in which other embedding is possible by the approach of this invention. The implant of drawing 4 includes the hole 308 with the coaxial screw thread of the center opened by the end 310 about this. Two or more splines 312 used for touching the auxiliary parts (not shown in drawing) and the interface like abutments from this end are extended upwards. This spline interface is indicated by U.S. Pat. No. 5,449,291 entitled "the prosthetic implant device in which it has feedback with a feel" at the detail.

[0084] Since deformation of a certain kind can be carried out to above-mentioned equipment and an above-mentioned approach, without separating from the range of this invention, it is contained in explanation, or the matters shown in the attached drawing are [no] for explanation, and restrict this invention.

[Translation done.]